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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/809,140 | 03/25/2004 | Hassan Chaouk | BioCure 260 | 7389 |
| 44260 | 7590 | 05/20/2005 | EXAMINER | |
| LAW OFFICE OF COLLEN A. BEARD, LLC | | | DANIELS, MATTHEW J | |
| P. O. BOX 1064 | | | ART UNIT | PAPER NUMBER |
| DECATUR, GA 30031-1064 | | | 1732 | |

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/809,140 | CHAOUK ET AL. |
| | Examiner | Art Unit |
| | Matthew J. Daniels | 1732 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 September 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 - 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/27/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. **Claims 1-8**, drawn to a method for extruding a string, classified in class 264, subclass 165.
 - II. **Claims 9-12**, drawn to a hydrogel string, classified in class 524, subclass 916.
2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product could be made by another and materially different process such as stereolithography in a prepolymer bath to form a hydrogel string by photoinitiation.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and because the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Collen Beard on 3 May 2005, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Art Unit: 1732

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (USPN 6152943) in view of Tanabe (USPN 5443454). **As to Claim 1**, Sawhney teaches a method for forming a hydrogel comprising the steps: providing a delivery device having a

gelation chamber (Fig. 3); providing a prepolymer composition that will form a hydrogel when brought into contact with a gelation initiator (2:64-3:6); contacting the prepolymer with the gelation initiator in the gelation chamber so that it forms a hydrogel in the gelation chamber (10:1-24); and extruding the hydrogel from the delivery device (Fig. 5A and 10:15-17). Sawhney appears to be silent to forming or extruding a string. However, this aspect of the invention would have been obvious over Tanabe, who teaches liquid substances introduced through lumen into a mixing chamber (Fig. 8A, Item 40c) and reactively solidifying to form a solid line or filament (13:44-54). It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine the method of Tanabe with that of Sawhney in order to eliminate the dispersing and leakage of an embolic material out of the site of an aneurysm (Tanabe, 4:48-59). **As to Claim 2**, both Sawhney (Figs. 3 and 4) and Tanabe (Fig. 8A) teach a catheter delivery device. **As to Claim 3**, both Sawhney (Fig. 3, Items 49 and 49') and Tanabe (Figs. 8A, 8B, 9A) teach a multilumen catheter. **As to Claim 4**, both Sawhney (Fig. 3, Item 46) and Tanabe (Fig. 8A, Item 40c) teach a gelation chamber. **As to Claim 5**, Tanabe teaches a catheter that is coaxial having an inner catheter and an outer catheter and the method further comprising the step of sliding the inner catheter within the outer catheter to increase or decrease the length of the gelation chamber (14:16-18). **As to Claim 6**, Sawhney teaches a method wherein the prepolymer composition comprises at least two solutions that will form a hydrogel when combined in the gelation chamber (7:1-14 and 10:1-24). **As to Claim 7**, it would have been obvious or inherent in the method of Sawhney that hydrogel would have been extruded as prepolymer composition was moved to the gelation chamber (10:1-24). **As to Claim 8**, Sawhney teaches a hydrogel being formed in the gelation chamber, but is silent to the other

Art Unit: 1732

claimed limitations. However, Tanabe teaches a delivery device that is a coaxial dual lumen catheter and the inner catheter is slidable within the outer catheter so that the degree of polymerization can be altered as the inner catheter is slid towards the distal end of the gelation chamber (14:16-18).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Examiner cites McCrory (USPN 6,139,520), Felt (USPN 6140452) and Biocure, Inc. (WO 01/68720) as indication of the state of the art at the time of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Daniels whose telephone number is (571) 272-2450. The examiner can normally be reached on Monday - Friday, 8:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJD 5/3/05



MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER